REMARKS

Claims 1-10 were previously pending in this application. Claims 1, 4 and 5 have been amended, non-elected claim 3 has been canceled without prejudice to or disclaimer of the underlying subject matter, and new claims 11-17 have been added. Support for the new and amended claims can be found throughout the specification, for example, at page 15, lines 4-21, page 23, line 21 through page 24, line 19, in the sequence listing, and in the claims as originally filed. Claim 5 has also been amended to more properly depend from claim 4. The specification has been amended at the request of the Examiner to remove hyperlinks and browser executable code and to correct typographical errors. No new matter enters by way of these amendments.

1. Restriction/Election

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants further acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants submit that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide

sequences to be claimed in a single application." (M.P.E.P., 8th ed., rev. 1, February 2003, Section 803.04). The MPEP further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Although Applicants disagree with the election requirement of a single nucleotide sequence, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 13.

2. Specification – Browser Executable Code

The specification has been objected to for purportedly containing "embedded hyperlink and/or other form of browser-executable code." Office Action at page 3

The purpose of the requirement that hyperlinks or other forms of browser executable code be removed from the specification is so that on the United States Patent and Trademark Office website, one cannot click on the hyperlink and be transported to another, potentially commercial, website. This requirement does not exclude the listing of a website that is not present as a hyperlink.

Applicants have amended the specification to remove the phrase "http://" and embedded hyperlinks (instead listing the websites using the format www-websitename.html). Although it is possible to click on this purported "hyperlink" in a Microsoft Word document and be transported to the corresponding website, or even to copy and paste this purported "hyperlink" into the address location in Microsoft Explorer,

this purported "hyperlink" would not be usable when placed on the United States Patent and Trademark Office website. For example, a search of the United States Patent and Trademark Office patent database using "www.ncbi.nlm.nih.gov" identified 61 patents citing this website, including USPN 6,552,250. In the '250 patent, the citation of this website using the exact format used by the Applicants does not result in a useable hyperlink. Therefore, the citation of a website in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application.

In light of these remarks, applicants respectfully request withdrawal of this objection to the specification.

3. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 1, 2, and 4-10 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Office Action at page 3.

Claim 1 is allegedly indefinite in the recitation of the phrase "fragment thereof" because "no lower limit for the fragment size is recited." Office Action at page 3. Applicants respectfully disagree. A grammatically consistent interpretation of the claim at issue would relate the phrase "fragment thereof" in the preamble back to the phrase "plant protein" directly preceding it. Thus, the skilled artisan would understand that the claimed nucleic acid molecule encodes a plant protein or fragment thereof and no lower limit for the fragment size need be recited. Based on the foregoing, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

Claims 1, 4, and 5 are allegedly indefinite "because they claim more than was elected." Office Action at page 3. Claims 1, 4, and 5 have been amended to claim the subject matter elected in the Response to Restriction Requirement filed on June 10, 2003. In view of these amendments, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

Claims 4 and 5 are allegedly indefinite for the recitation of "structural nucleic acid molecule." Office Action at page 3. The Examiner alleges that this language is indefinite "because the instant application does not distinguish a structural nucleic acid from a non-structural nucleic acid." *Id.* Applicants respectfully disagree. Applicants respectfully point out that the claims are to be read in light of the specification. *See In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert. denied*, 112 S. Ct. 169 (1991).

Applicants respectfully assert that the meaning of the phrase "structural nucleic acid molecule" is readily understandable by one of skill in the art, particularly when considered in the context of the other phrases of claims 4 and 5 and the specification. *See, e.g.*, Specification at page 13, lines 11 through 16. Moreover, one skilled in the art would readily recognize the distinction between a structural nucleic acid molecule and a non-structural nucleic acid molecule. Applicants therefore respectfully request reconsideration and withdrawal of the indefiniteness rejection of claims 4 and 5 under 35 U.S.C. § 112, second paragraph.

4. Claim Rejections – 35 U.S.C. § 101

Claims 1, 2, and 4-10 have been rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. Office Action page 3. In particular, the Examiner alleges that the specification "does not disclose a specific, substantial, and credible utility for either SEQ ID NO: 8[1] or a polypeptide encoded by SEQ ID NO: 13 nor is a specific, substantial, and credible utility apparent to one of skill in the art from the disclosure and what is known in the art." *Id.* Applicants respectfully disagree with the Examiner.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). The instant specification discloses many utilities that satisfy this requirement. One such utility is the use of the claimed nucleic acid molecule in genetic mapping. Specification at page 43, line 31, through page 45, line 19. Another one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 35, line 21 through page 43, line 30. Further uses of the claimed nucleic acid molecules are provided for at page 30, *et. seq.*, under the heading "Uses of the Agents of the Invention." Many of these utilities, including the utilities argued above, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize nucleic acid

[1] In Applicants' Response to Restriction Requirement mailed June 10, 2003, Applicants elected with traverse, to prosecute group I as drawn to SEQ ID NO: 13. The Examiner's citation to SEQ ID NO: 8 is treated herein as a typographical error.

molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. The Examiner ignores the disclosed utilities, and simply argues that the claimed invention lacks patentable utility, but does not provide **any** support (legal or factual) for the proposition that these utilities are not legal utilities.

The Examiner has not provided **any** evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. The Examiner "must do more than merely question operability - [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic

acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Thus, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. §101.

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1, 2, and 4-10 under 35 U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

5. Claim Rejections – 35 U.S.C. § 112, first paragraph, enablement

Claims 1, 2, and 4-10 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled). Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

6. Claim Rejections – 35 U.S.C. § 102(b)

Claim 1 has been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Seiberler *et al.* (EMBO J. 13: 3481 (1994)) ("Seiberler, *et al.*"). Applicants respectfully traverse this rejection.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or

device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q 619 (Fed. Cir. 1985). In the present application, amended claim 1 is directed to isolated nucleic acid molecules encoding plant proteins or fragments thereof comprising the nucleic acid sequence of SEQ ID NO: 13. The reference cited by the Examiner does not disclose SEQ ID NO: 13 in its entirety. The Examiner has applied an untenable interpretation of the claims to cover small fragments of the specifically claimed nucleic acid molecule, *i.e.*, molecules as short as a single codon, and thus concludes that the claim is anticipated by the cited reference. Office Action at page 4. A grammatically consistent interpretation of the claim at issue would relate the phrase "or fragment thereof" in the preamble back to the phrase "plant protein" directly preceding it.

As such, the presently amended claims are not anticipated by Seiberler, *et al.*, cited by the Examiner. Whatever else Seiberler *et al.* teaches, it does not disclose SEQ ID NO: 13 in its entirety. Absent a teaching of each and every element of the claim, *i.e.*, SEQ ID NO: 13, the reference cited by the Examiner does not anticipate claim 1 and the rejection should be reversed.

Accordingly, for at least the foregoing reasons, the rejection of claim 1 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

Thomas E. Holsten (Reg. Agent No. 46,098)
Holly Logue Prutz (Reg. Atty No. 47,755)
David R. Marsh (Reg. Atty No. 41,408)

ARNOLD & PORTER
555 Twelfth Street, NW
Washington, D.C. 20004
(202) 942-5000 telephone
(202) 942-5999 facsimile

Date: November 25, 2003

Correspondence Address:
MONSANTO COMPANY
800 N. Lindbergh Blvd.
Mailzone N2NB
St. Louis MO 63167
(314) 694-3602 telephone
(314) 694-1671 facsimile